

REMARKS

With the entry of the present Amendment, claims 1, 5-11, 13-15 and 46 are in this application. Claim 1 has been amended to better claim the invention, i.e., to clarify that a sequence of 15 or more consecutive nucleotides. Support is found in the as-filed Specification at page 22, line 1, with the recitation of "contiguous," which has the same meaning as consecutive in this context. None of the amendments made herein constitutes the addition of new matter. The amendments made herein are believed to place this case in condition for allowance or to simplify the issues for appeal.

The Drawings

Applicants note that the present application was filed under 35 U.S.C. 371; accordingly, it is respectfully submitted that there should be no requirement for Formal Drawings. The Office Action does not state that Formal Drawings are required at this time.

The Rejections under 35 U.S.C. 112, first paragraph

Claims 1, 5-11 and 13-15 remain rejected under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter which was not described in the Specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, has possession of the claimed invention. Applicants respectfully traverse this rejection.

In the interest of advancing prosecution and without acquiescing to the rejection, Applicants have amended claim 1 in accordance with the suggestion of the Examiner, i.e., to recite nucleotides 1147-1740 of SEQ ID NO:1, or a portion consisting of 15 consecutive

nucleotides of the nucleotides set forth in SEQ ID NO:1. This amendment is supported by context of the as-filed Specification, for example at page 22, line 1.

Applicants respectfully submit that the amendment of claim renders this rejection moot, and the withdrawal of the rejection is respectfully requested.

The Rejections under 35 U.S.C. 112, second paragraph

Claims 1, 5-11 and 13-15 have been rejected under 35 U.S.C. 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter Applicants regard as the invention. Applicants respectfully traverse this invention.

In Item 23 of the current Office Action, the Examiner has indicated that recitation of "consecutive" nucleotides of nucleotides 1147-1740 of SEQ ID NO:1 would resolve the issue of alleged indefiniteness.

In the interest of advancing prosecution and without acquiescing to the rejection, claim 1 has been amended to recite a sequence of 15 or more consecutive nucleotides, in accordance with the Examiner's suggestion. Allowance of the claims is now respectfully requested.

The Rejections under 35 U.S.C. 102

Claims 1, 5-9, 13-15 and 46 have been rejected under 35 U.S.C. 102(b) as allegedly anticipated by Gardner et al. (1993, Nucleic Acids Research). Applicants respectfully traverse this rejection.

In the interest of advancing prosecution and without acquiescing to this rejection, claim 1 has been amended to specify the particular sequence of the probe or primer used in the detection methods, namely, nucleotides 1147-1740 of SEQ ID NO:1 or a probe or primer of at least 15 consecutive nucleotides thereof (or a complementary sequence).

Moreover, the Gardner reference makes no teaching of a method for detecting Plasmodium organisms in biological samples by hybridization or by polymerase chain reaction. The Gardner reference discusses the relatedness of certain sequences across a variety of organisms, including yeast, bacteria, filamentous fungi, algae and plants. In fact, Table 1 on page 1070 of the cited 1993 Gardner reference includes 44 segments of segments of plasmodium sequence, which were conserved in comparison to *E. coli* sequences. The Gardner (1993) reference does not show the use of the particular sequence (nucleotides 1147-1740 or a 15 consecutive-nucleotide probe or primer derived in sequence therefrom) in detection methods.

With respect to arguments previously provided, it appears that the Examiner has not noted that arguments related to teachings of the sequence of the probe or primer were in respect of the rejection, now withdrawn, over the Gardner (1994) reference.

In view of the foregoing discussion and the amendment to the claims, Applicants respectfully maintain that the invention as claimed is not anticipated by the cited Gardner reference, and withdrawal of the rejection is requested.

The Rejection under 35 U.S.C. 103(a)

Claims 14-15 have been rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Gardner et al. (1993) in view of Obst et al. (1990). Applicants respectfully traverse this rejection.

The cited Gardner reference is said to teach a method of detecting a human plasmodium malarial agent in a biological sample, by contacting a blood-derived (erythrocyte) sample with a probe or primer that comprises a LSU rRNA nucleic acid sequence of SEQ ID NO:1, nucleotides 1147-1740 that is conserved and found in an extra chromosomal element

Applicants have discussed the Gardner (1993) reference above. This reference relates to an analysis of sequence relatedness across a wide variety of organisms, and there is no teaching or suggestion of SEQ ID NO:1, nucleotides 1147-1740, or other plasmodium sequence, as useful in methods for detection of plasmodial species in biological samples. There appears to be no discussion of the sequence relatedness for the noted sequence among different species of Plasmodium.

The Obst et al. reference relates to mapping sequences on plant chromosomes and to localizing nuclear sequences in *Plasmodium berghei* in blood smears. Unique nuclear sequences and rRNA probes were used in the experiments described. There is no indication in this reference that the use of probes or primers of the sequences encompassed by that recited in claim 1 would be useful in methods for detection of a Plasmodium in a biological sample, and there is no discussion of the conservation of the recited sequence among Plasmodium species.. At most, this reference would provide an invitation to experiment, but there is no teaching or suggestion of the specifically claimed methods nor is there any provision of any reasonable probability of success in the claimed methods.

Applicants respectfully submit that there is no motivation provided in the cited references for their combination. The cited 1993 Gardner reference discusses phylogenetic relationships based on a subset of rRNA sequences. The cited Obst

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reference shows hybridization of a relatively large probe to a slide of *Plasmodium berghei*, but provides no teaching as to the sequence relatedness for other species of Plasmodium. The context appears to be detection of particular sequences but not carrying out a sensitive and reliable method to detect the organism *per se*.

In the absence of the cited references providing a reasonable probability of success, as required by In re O'Farrell, 7 U.S.P.Q.2d 1673 C.A.F.C, 1988, Applicants respectfully state that the invention as claimed is not *prima facie* obvious over the cited references, and the rejection should be withdrawn.

Conclusion

This Amendment is accompanied by a Notice of Appeal, a Petition for Extension of Time (one month) and a check in the amount of \$220.00 as required by 37 C.F.R. 1.16. It is believed that the present submission does not require the payment of any additional fees under 37 C.F.R. 1.16-1.17. If this is incorrect, please charge any deficiency or credit any overpayment due under the foregoing Rules to Deposit Account No. 07-1969.

Respectfully submitted,



Donna M. Ferber
Reg. No. 33,878

GREENLEE, WINNER AND SULLIVAN, P.C.
5370 Manhattan Circle, Suite 201
Boulder, CO 80303
Telephone (303) 499-8080
Facsimile: (303) 499-8089
Email: winner@greenwin.com
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